UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

IN RE: COLUMBIA UNIVERSITY PATENT LITIGATION	**MDL NO. 1592**
IMMUNEX CORPORATION, a Washington Corporation and AMGEN INC., a Delaware Corporation,	**CIVIL ACTION NO.: 04-10740-MLW**
	C. D. Cal. No. CV 03-4349 MRP (CWx)
Plaintiffs,	**Judge Mark L. Wolf**
vs.	
THE TRUSTEES OF COLUMBIA UNIVERSITY in the City of New York, a New York Corporation,	
Defendant.	
AND RELATED COUNTERCLAIM.	

MEMORANDUM OF POINTS AND AUTHORITIES
IN SUPPORT OF MOTION OF PLAINTIFFS
AMGEN INC. AND IMMUNEX CORPORATION
TO CONSOLIDATE ACTION NO. 04-12626 MLW WITH THIS PROCEEDING

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INTRODUCTION

Efficiency dictates that this action be consolidated with *Amgen Manufacturing, Ltd., Immunex Rhode Island Corporation, and Amgen USA, Inc. v. Trustees of Columbia University*, Action No. 04-12626 MLW. That action (hereafter the "Amgen Affiliates action") was filed by certain affiliates of Amgen to raise, on their own behalf, certain of the same issues that were raised and are raised by Amgen and other plaintiffs in this MDL proceeding. Although some of the legal theories presented in this MDL proceeding have been mooted by Columbia's Covenant Not To Sue Amgen – a Covenant that does not extend to the Amgen Affiliates – the facts still at issue in this MDL proceeding (under contract and tort theories) substantially overlap with the facts at issue in the Amgen Affiliates action.

When Columbia sought transfer of Amgen's action to the Northern District of California, and again when Columbia successfully sought transfer of these cases by the Judicial Panel on Multidistrict Litigation, Columbia argued that separate "complex and time-consuming" discovery of the overlapping fact issues in these cases would be inefficient, that separate litigation would require "the same witnesses" to testify on multiple occasions "for the same issues in each of the lawsuits" because "witnesses would face the unreasonable burden of giving the exact same testimony on multiple occasions," and that separate litigation would be "duplicative and wasteful" and would present "the untenable risk of inconsistent rulings" Columbia Memo. of P. & A. in Supp. of Mot. to Transfer, Oct. 27, 2003, p. 7, attached hereto as Exhibit A; Columbia University's Br. in Supp. of Mot. to Transfer under 28 U.S.C. § 1407, Nov. 25, 2003, pp. 1, 7-8, attached hereto as Exhibit B. Consolidation is even more proper now than when Columbia forced consolidation of these actions, since this Court has become very familiar with these cases.

STATEMENT OF THE FACTS

The claims in the MDL proceeding and the Amgen Affiliates action arise from a series of events which, as the Court has already described, date back to 1980, when patent application No. 06/124,513 (the "'513 application") was filed for technology involving the use of recombinant DNA and a process of co-transformation to produce proteins in host cells which do not normally produce those proteins. *Biogen Idec MA Inc. v. The Trs. of Columbia Univ. in the City of New York*, 332 F. Supp. 2d 286, 288-291 (D. Mass. 2004). From the '513 application, four patents have issued, known as the "Axel patents," three of which have expired (the "prior issued Axel patents") and the fourth of which, U.S. Patent No. 6,455,275 (the "'275 patent"), issued on September 24, 2002.

In response to demands by Columbia that its licensee pharmaceutical companies pay royalties under the '275 patent, those companies (including Amgen) filed the actions that became the MDL proceeding. Plaintiffs in the MDL proceeding challenged the '275 patent as invalid and unenforceable on a number of grounds, including prosecution laches (because of Columbia's unreasonable and unexplained delay in the circuitous prosecution leading to the '275 patent), double patenting, and inequitable conduct before the Patent and Trademark Office ("PTO"). This Court has previously had occasion to review the facts that show that the '275 patent is likely both invalid for double patenting and unenforceable due to prosecution laches. *See Biogen Idec MA Inc. v. The Trs. of Columbia Univ. in the City of New York*, 332 F. Supp. 2d 286, 297 (D. Mass. 2004).

Days after Plaintiffs provided initial expert reports to Columbia on August 27, 2004 detailing the bases for their double patenting contentions, and shortly before Columbia was due to file its responsive reports on September 17, Columbia filed on September 2 a limited "Covenant Not To Sue" (the "Covenant") and an "Emergency Motion" to dismiss portions of the MDL proceeding. To address some of the defects in the Covenant, Columbia expanded its Covenant in open court on October 6, and by Order of November 5, 2004, this Court granted

Columbia's motion to dismiss. *In re Columbia Univ. Patent Litig.*, 343 F. Supp. 2d 35 (D. Mass. 2004).

The Court's Order does not, however, terminate all of the litigation between Columbia and Amgen. Claims remaining at issue between them include:

- Amgen's request for a declaration that additional royalties are not due under the parties' license agreement for periods after August 16, 2000, entirely apart from the issue of the validity or enforceability of the '275 patent (First Claim for Relief);
- Amgen's request for a declaration that Columbia's misconduct in connection with the events leading to and concerning the Axel patents constitutes "repressive practices" in breach of the license agreement, such that *inter alia* "payment of the royalties claimed by Columbia is excused" (Seventh Claim for Relief);[1] and
- Columbia's counterclaims against Amgen, seeking declaratory relief and royalties supposedly owed, as to which Amgen has asserted defenses (e.g., unclean hands) that flow from the same pattern of Columbia's misconduct leading to and concerning the Axel patents.[2]

Columbia's Covenant, even as expanded, expressly excludes from its scope any non-party affiliates of the plaintiffs in the MDL proceeding, even where those affiliates engage in the identical *conduct* that Columbia alleged was covered by the claims of the '275 patent. As the Court noted at the October 6 hearing, those affiliates were not before the Court, and the proper procedural method to bring their situation before the Court would be for affiliates of Amgen to file their own action:

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[1] As the Court has recognized, the National Institutes of Health "required that 'any license granted by [Columbia] . . . shall include adequate safeguards against unreasonable royalties and repressive practices.'" *Biogen Idec MA, Inc. v. The Trs. of Columbia Univ. in the City of New York*, 332 F. Supp. 2d 286, 291 (D. Mass. 2004).

[2] Amgen has also filed a motion for leave to amend to add to its complaint certain facts occurring or discovered after the filing of its pending complaint, including a ruling that Amgen should recover back royalties overpaid by mistake (proposed amended First Claim for Relief) and a declaration that Columbia's misconduct in connection with the prior issued Axel patents renders them unenforceable and that Columbia cannot claim royalties under them (proposed amended Third Claim for Relief).

> [I]f there's what [Amgen's counsel] call an affiliate that's not a party to this case and if I dismiss this case, then that affiliate can file its own case the way Idec did.

Hearing Transcript, Oct. 6, 2004, p. 131.

Accordingly, following this Court's ruling on November 5, those Amgen Affiliates brought the Amgen Affiliates action, setting forth the fact that they are engaged for Amgen in the conduct that Columbia claimed was covered by the '275 patent, and seeking in their own right the rulings regarding the invalidity and unenforceability of the '275 patent that the plaintiffs in the MDL proceeding sought.

The overlap between the claims originally brought in the MDL proceeding and the claims in the Amgen Affiliates action is extensive, in that the cases raised against the same defendant the validity and enforceability of the same '275 patent on similar grounds. Moreover, because the underlying facts are still at issue on various contractual and tort theories in the MDL proceeding, there is also substantial overlap of the facts pertinent to this MDL proceeding and to the claims in the Amgen Affiliates action. Examples of this overlap are detailed in the table attached hereto as Exhibit C.

Amgen now moves to consolidate the Amgen Affiliates action with this MDL proceeding in order to promote judicial economy, economy for the parties, and consistency of results.

I. THE ACTIONS HAVE A COMMON PARTY AND COMMON ISSUES OF FACT OR LAW.

In determining whether to order consolidation, the court must first ask whether the two proceedings involve a common party and common issues of fact or law. *Seguro de Servicio de Salud de Puerto Rico v. McAuto Sys. Group, Inc.*, 878 F.2d 5, 8 (1st Cir. 1989). Once that determination has been made, the court has "broad discretion in weighing the costs and benefits of consolidation to decide whether that procedure is appropriate." *Id.* If the threshold questions are resolved in favor of consolidation, it will usually be allowed unless the opposing party can demonstrate prejudice. *Id.*

Willard v. Town of Lunenburg, 202 F.R.D. 57, 59 (D. Mass. 2001); *see also In re PRI Automation, Inc. Sec. Litig.*, 145 F. Supp. 2d 138,140 (D. Mass. 2001) (motion to consolidate ordinarily will be granted unless the opposing party shows "'demonstrable prejudice'").

Consolidation requires only a common party and "a common question of law or fact," and "consolidation of actions for trial which appear to be of like nature and concern themselves with the same or similar questions rests within the sound discretion of the trial court, and its action thereon will not be disturbed on appeal except for the abuse of discretion." *Skirvin v. Mesta*, 141 F.2d 668, 672-73 (10th Cir. 1944). Where a consolidation of validity, infringement and unfair competition claims against different defendants "would best promote the efficient and expeditious resolution" of the claims, consolidation is appropriate, notwithstanding the fact that different defendants and different products are involved. *Procter & Gamble Co. v. Nabisco Brands, Inc.*, 604 F. Supp. 1485, 1493 (D. Del. 1985) (plaintiff patentee's motion granted to consolidate for trial three infringement actions it filed against different defendants).

These requirements are satisfied here. Columbia is the common defendant in the actions sought to be consolidated. And the overlapping issues of fact are numerous. For example, the pattern of misconduct of Columbia before the PTO regarding all of the Axel patents is relevant both to the Amgen Affiliates' claims that the '275 patent is unenforceable and to Amgen's claims that it owes no royalties to Columbia[3] and that Columbia failed to meet its obligations under the license agreement to refrain from "repressive practices" – issues that affect Columbia's purported termination of the License Agreement that protects both Amgen and the Amgen Affiliates. As Columbia argued in obtaining transfer of these cases to this Court:

> [T]he close similarity between the complaints carries over to allegations relating to Columbia's obligations under a letter agreement with the National Institute [sic] of Health ("NIH") not to engage in "repressive royalty practices." Six

[3] Columbia has argued elsewhere that Amgen would still owe royalties for times before it gave notice to Columbia that it was going to challenge the patent, citing *Studiengesellschaft Kohle v. Shell Oil Co.*, 112 F.3d 1561 (Fed. Cir. 1997). Columbia Br. in Opp. to Amgen's Mot. to Amend and Supplement Compl., Dec. 22, 2004, p. 7, n. 3. But that case concerned an innocent licensor of an invalid patent, not a licensor who made misrepresentations to the Patent and Trademark Office to obtain the patent. In such a case, a licensee should not be required to pay royalties. *See Lear, Inc. v. Adkins*, 395 U.S. 653, 670 (1969).

> Plaintiffs explicitly present claims relying upon these obligations, while the other six Plaintiffs refer to these obligations in their charging allegations. Moreover, every Plaintiff serving discovery upon Columbia has requested the production of documents on this issue . . . .

Columbia University's Reply Br. in Supp. of Mot. to Transfer under 28 U.S.C. § 1407, Jan. 19, 2004, p. 5. Moreover, the claims of the prior expired Axel patents will need to be construed in connection with Amgen's claim of overpayment of royalties based on products not covered by those patents, as well as to address the merits of the Amgen Affiliates' claim that the '275 patent is invalid for double patenting. Columbia cited the overlapping need for construction of claims as a primary reason to justify the transfer of these actions under 28 U.S.C. § 1407 which allows transfer where there are "common questions of fact,"[4] and that overlap is even more appropriately a justification for consolidation under Rule 42(a) which allows consolidation where there is "a common question of *law or* fact" (emphasis added). Additional examples of factual overlap among the cases are detailed in the table attached hereto as Exhibit C.

II. THE DISCRETION TO CONSOLIDATE IS BROADLY CONSTRUED TO PROMOTE JUDICIAL ECONOMY.

Federal Rule of Civil Procedure 42(a) provides broad discretion to consolidate cases:

> When actions involving a common question of law or fact are pending before the court, it may order a joint hearing or trial of any or all the matters in issue in the actions; it may order all the actions consolidated; and it may make such orders concerning proceedings therein as may tend to avoid unnecessary costs or delay.

This rule "was designed and intended to encourage such consolidation where possible." *United States v. Knauer*, 149 F.2d 519, 520 (7th Cir. 1945), *aff'd*, 328 U.S. 654 (1946) (consolidation of petitions to revoke naturalization certificates of 14 defendants); *see also Switzenbaum v. Orbital Sciences Corp.*, 187 F.R.D. 246, 248 (E.D. Va. 1999) (consolidating 18 securities class actions, noting that "[j]udicial economy generally favors consolidation"); *Barcelo v. Brown*, 78 F.R.D. 531, 535-36 (D.P.R. 1978) (consolidating actions seeking redress for environmental and other damages to the Island of Vieques; court noting that "[t]he paramount

[4] Columbia University's Reply Br. in Supp. of Mot. to Transfer under 28 U.S.C. § 1407, Jan. 19, 2004, pp. 9-10, attached hereto as Exhibit D ("Multiple claim construction proceedings would be wasteful and inefficient." and "Just as with validity, the starting point of every infringement analysis is claim construction.").

objective of consolidation is the accomplishment of great convenience and economy in the administration of justice").

The efficiency resulting from consolidation is very significant in this instance – for the Court, for the parties, for witnesses and for any jury. Given the progress of these MDL proceedings, and the fact that the MDL proceeding and the Amgen Affiliates action are already pending before the same Court, it would be inefficient for the Court to oversee discovery and other proceedings regarding the history of Columbia's activities leading to and regarding the Axel patents separately in different actions. Columbia itself so argued – successfully – in its motion to the J.P.M.L. Columbia's Br. in Supp. of Mot. to Transfer, Oct. 27, 2003, pp. 6-12, attached hereto as Exhibit A. The J.P.M.L. found that "common questions of fact" meant that centralization of the actions would "serve the convenience of the parties and witnesses and promote the just and efficient conduct of the litigation." Transfer Order, April 8, 2004, pp. 1-2, attached hereto as Exhibit E.

Consolidation of multiple actions for declaration of patent invalidity is proper in a court that has acquired significant familiarity with the same basic technology and the alleged infringing activities. Such consolidation prevents unnecessary cost and delay and promotes the interest of judicial economy. *Hooker Chems. & Plastics Corp. v. Diamond Shamrock Corp.*, 96 F.R.D. 46, 49 (W.D.N.Y. 1982) ("In view of the fact that the same basic cell technology, the same parties, and the same alleged infringing actions are presented by both of the actions, the court shall order consolidation . . . in order to 'avoid unnecessary cost or delay' and in the interest of judicial economy").

Although the cases are already pending before the same Court, consolidation would also promote consistent outcomes if juries are needed. *Hendrix v Raybestos-Manhattan, Inc.*, 776 F.2d 1492, 1495 (11th Cir. 1985) (court should consider whether any risk of confusion is "'overborne by the risk of inconsistent adjudications of common factual and legal issues'"); *Arnold v. Eastern Air Lines, Inc.*, 681 F.2d 186, 193 (4th Cir. 1982), *cert. denied*, 460 U.S. 1102 (1983) and 464 U.S. 1040 (1984) (question is whether the risks of prejudice or confusion are

"overborne by the risk of inconsistent adjudications of common factual and legal issues, the burden on parties, witnesses and available judicial resources . . . , the length of time required to conclude multiple suits . . ., and the relative expense to all concerned").

There is no reason to imagine that confusion or other prejudice would result from the consolidation of the Amgen Affiliates action with these proceedings. Indeed, the Amgen Affiliates simply raise the same issues previously raised by the plaintiffs *in* the MDL proceeding before the Covenant was issued.

Nor would consolidation result in any significant delay. Discovery has generally been stayed in the MDL proceedings – indeed, initial disclosures have not yet occurred – so they are not significantly advanced as to fact discovery.

CONCLUSION

For the reasons set forth above, Amgen respectfully requests that the Amgen Affiliates action be consolidated with this MDL proceeding.

Dated: January 19, 2005.

Respectfully submitted,

IMMUNEX CORPORATION, a Washington Corporation and AMGEN INC., a Delaware Corporation
By their attorneys,

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